UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,737	03/09/2004	Daniel Henry VanCamp	10177-197-999	3400

20583 7590 04/15/2008

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
OU, JING RUI	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
04/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/797,737	VANCAMP, DANIEL HENRY	
	Examiner	Art Unit	
	JING OU	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *2,13, and 28-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-12 and 14-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/10/2005, 12/09/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the Election/Restriction response filed on March 04, 2008. Claims 1-41 are pending. Claims 1, 13, 14, 27, 28, and 41 are independent. Claims 2, 13, and 28-41 are withdrawn from consideration.

Election/Restrictions

2. Applicant elected Species C (Figure 3) in the reply filed on 03/04/2008. Applicant asserted that Claims 1-27 are readable on Species C (Figure 3). However, examiner disagrees. Claims 2 and 13 are not readable on Species C (Figure 3). Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 2, 13, and 28-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/04/2008.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinchuk et al (US Pat. No.: 6,348,066).

In regard to Claim 1, Pinchuk et al discloses an implantable system for treating a body lumen having a lumen wall comprising: (a) an outer balloon-expandable stent (400, Fig. 12 and Col. 1, lines 42-46, the stent is capable to be expanded by a balloon) comprising a first end (404, Fig. 12), a second end (402, Fig. 12), a surface, and a lumen (Col. 3, lines 65, the outer stent must have a lumen); and (b) at least one inner self-expanding stent (500, Fig. 12) comprising a first end (504, Fig. 12), a second end (502, Fig. 12), and a surface; wherein the inner stent is capable of being deployed so that: at least a portion of the inner stent is disposed within the lumen of the outer stent; and the first end of the inner stent is disposed outside the lumen of the outer stent (Fig. 12).

In regard to Claim 3, the outer stent is capable of exerting a radial force against the body lumen wall (the region pointed by 606, Fig. 12) that is greater than the radial force that the inner stent is capable of exerting against the body lumen wall (Fig. 12, stent 400 exerts force on the whole region of 606 whereas stent 500 only exerts force on the region 606 at its second end 502. Therefore, it is inherent that the stent 400 exerts a radial force against the body lumen wall that is greater than the radial force that the inner stent is capable of exerting against the body lumen wall).

In regard to Claim 14, Pinchuk et al discloses an implantable system for treating a body lumen having a lumen wall comprising: (a) an outer balloon-expandable stent (400, Fig. 12 and Col. 1, lines 42-46, the stent is capable to be expanded by a balloon) comprising a first end (404, Fig. 12), a second end (402, Fig. 12), a surface, and a lumen (Col. 3, lines 65, the outer stent must have a lumen); and (b) a first self-

expanding inner stent (500, Fig. 12 and Col. 1, lines 42-46, the stent is self-expandable)comprising a first end (504, Fig. 12), a second end (502, Fig. 12), and a surface; wherein the first inner stent is capable of being deployed so that the first end of the first inner stent is disposed outside of the lumen of the outer stent and the second end of the first inner stent is disposed within the lumen of the outer stent (Fig. 12).

In regard to Claim 15, the system further comprises a second inner self-expanding stent (300, Fig. 12 and Col. 6, lines 53-67 and Col. 7, lines 1-26 and Col. 1, lines 42-46, the stent is self-expandable) comprising a first end (302, Fig. 12), a second end (304, Fig. 12), and a surface; wherein the second inner stent is capable of being deployed so that the first end of the second inner stent is disposed outside of the lumen of the outer stent and the second end of the second inner stent is disposed within the lumen of the outer stent (Fig. 12 and Col. 6, lines 53-67 and Col. 7, lines 1-26).

In regard to Claim 16, the outer stent is capable of exerting a radial force against the body lumen wall (the region pointed by 606, Fig. 12) that is greater than the radial force that the first inner stent is capable of exerting against the body lumen wall (Fig. 12, stent 400 exerts force on the whole region of 606 whereas stent 500 only exerts force on the region 606 at its second end 502. Therefore, it is inherent that the stent 400 exerts a radial force against the body lumen wall that is greater than the radial force that the inner stent is capable of exerting against the body lumen wall).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 4-8, 10, 11, 17-21, 23, 24, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al (US Pat. No.: 6,348,066) in view of Brightbill (US Pub. No.: 2003/0204245).

In regard to Claim 4, Pinchuk et al discloses all the limitations of the claim but fails to disclose that the inner stent further comprises a coating comprising a biologically active material disposed on at least a part of the surface of the inner stent.

However, Brightbill explicitly discloses an inner stent (410, Fig. 4) that comprises a coating (412, Fig. 4) comprising a biologically active material disposed on at least a part of the surface of the inner stent (Fig. 4 and Paras.[0037], [0025], and [0030]).

Pinchuk et al and Brightbill are analogous art because they are from the same field of endeavor, stent.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Pinchuk et al and Brightbill before him or her, to modify the system of Pinchuk et al to include an inner stent that comprises a coating

comprising a biologically active material disposed on at least a part of the surface of the inner stent as taught by Brightbill.

The suggestion/motivation for doing so would have been to minimize undesirable reactions such as inflammation, infection, thrombosis, and proliferation of cell growth that occludes the passageway (Brightbill, Para.[0006]).

Therefore, it would have been obvious to combine Brightbill with Pinchuk et al to obtain the invention as specified in the instant claim.

In regard to Claim 5, the coating is disposed proximate the first end of the inner stent (Brightbill, Fig. 4).

In regard to Claim 6, the coating is disposed proximate the first end of the inner stent and proximate the second end of the inner stent (Brightbill, Fig. 4).

In regard to Claim 7, the surface of the inner stent is an outer surface (Brightbill, Para.[0012], the surface of the inner stent on which the biologically active material is disposed must be the outer surface).

In regard to Claim 8, the coating further comprises a polymeric material (Brightbill, Para.[0026], At the time of invention, applicant should note that it was well known in the art that a polymeric coating may serve to control the release of the biologically active material).

In regard to Claim 10, the outer stent (Brightbill, 420, Fig. 4) further comprises a coating (Brightbill, 422, Fig. 4) comprising a biologically active material disposed on at least a part of the surface of the outer stent (Brightbill, Fig. 4 and Paras.[0037], [0025], and [0030]).

In regard to Claim 11, the coating further comprises a polymeric material (Brightbill, Para.[0026], At the time of invention, applicant should note that it was well known in the art that a polymeric coating may serve to control the release of the biologically active material).

In regard to Claim 17, Pinchuk et al discloses all the limitations of the claim but fails to disclose that the first stent further comprises a first coating comprising a biologically active material disposed on at least a part of the surface of the first inner stent.

However, Brightbill explicitly discloses an first inner stent (410, Fig. 4) that comprises a first coating (412, Fig. 4) comprising a biologically active material disposed on at least a part of the surface of the first inner stent (Fig. 4 and Paras.[0037], [0025], and [0030]).

Pinchuk et al and Brightbill are analogous art because they are from the same field of endeavor, stent.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Pinchuk et al and Brightbill before him or her, to modify the system of Pinchuk et al to include an inner stent that comprises a coating comprising a biologically active material disposed on at least a part of the surface of the inner stent as taught by Brightbill.

The suggestion/motivation for doing so would have been to minimize undesirable reactions such as inflammation, infection, thrombosis, and proliferation of cell growth that occludes the passageway (Brightbill, Para.[0006]).

Therefore, it would have been obvious to combine Brightbill with Pinchuk et al to obtain the invention as specified in the instant claim.

In regard to Claim 18, the coating is proximate the first end of the first inner stent (Brightbill, Fig. 4).

In regard to Claim 19, the second stent (Brightbill, 430, Fig. 4) comprises a second coating (Brightbill, 432, Fig. 4) comprising a second biologically active material disposed on at least a part of the surface of the second stent (Brightbill, Fig. 4).

In regard to Claim 20, the second coating is disposed on a part of the surface of the second stent that is proximate the first end of the second stent (Brightbill, Fig. 4).

In regard to Claim 21, at least one of the first coating or second coating is polymeric material (Brightbill, Para.[0026], At the time of invention, applicant should note that it was well known in the art that a polymeric coating may serve to control the release of the biologically active material).

In regard to Claim 23, the outer stent (Brightbill, 420, Fig. 4) comprises a third coating (Brightbill, 422, Fig. 4) comprising a third biologically active material disposed on at least a part of the surface of the outer stent (Brightbill, Fig. 4).

In regard to Claim 24, the third coating further comprises a polymeric material (Brightbill, Para.[0026], At the time of invention, applicant should note that it was well known in the art that a polymeric coating may serve to control the release of the biologically active material).

In regard to Claim 26, the first coating is disposed on the outer surface of the first inner stent and the second coating is disposed on the outer surface of the second inner

stent (Brightbill, Paras.[0012] and [0026] and Fig 4. The first coating must be disposed on the outer surface of the first inner stent and the second coating must be disposed on the outer surface of the second inner stent. At the time of the invention, applicant should note that it was well known in the art that a stent coating comprises of a polymeric material and a biologically active material is usually disposed on the outer surface of the stent).

In regard to Claim 27, Pinchuk et al discloses an implantable system for treating a body lumen having a lumen wall comprising: (a) an outer balloon-expandable stent (400, Fig. 12 and Col. 1, lines 42-46, the stent is capable to be expanded by a balloon) comprising a first end (404, Fig. 12), a second end (402, Fig. 12), a surface, and a lumen (Col. 3, lines 65, the outer stent must have a lumen); (b) a first inner self-expanding stent (500, Fig. 12 and Col. 1, lines 42-46, the stent is self-expandable) comprising a first end (504, Fig. 12), a second end (502, Fig. 12), and a surface; and (c) a second inner self-expanding stent (300, Fig. 12 and Col. 6, lines 53-67 and Col. 7, lines 1-26 and Col. 1, lines 42-46, the stent is self-expandable)comprising a first end (302, Fig. 12), a second end (304, Fig. 12), and a surface; wherein: the first inner stent is capable of being deployed so that the first end of the first inner stent is disposed outside of the lumen of the outer stent and the second end of the first inner stent is disposed within the lumen of the outer stent; and the second inner stent is capable of being deployed so that the first end of the second inner stent is disposed outside of the lumen of the outer stent and the second end of the second inner stent is disposed within the lumen of the outer stent (Fig. 12 and Col. 6, lines 53-67 and Col. 7, lines 1-26).

Pinchuk et al does not appear to disclose the first inner stent comprises a first coating comprising a first biologically active material disposed on at least a part of the surface of the first inner stent proximate the first end of the first inner stent ; the second inner stent comprises a second coating comprising a second biologically active material disposed on at least a part of the surface of the second inner stent proximate the first end of the second inner stent; and the outer stent comprises a third coating comprising a third biologically active material disposed on at least a part of the surface of the outer stent.

However, Brightbill explicitly teaches a first inner stent (410, Fig. 4) that comprises a first coating (412, Fig. 4) comprising a first biologically active material disposed on at least a part of the surface of the first inner stent proximate the first end of the first inner stent (Fig. 4 and Paras.[0037], [0025], and [0030]); a second stent (430, Fig. 4) that comprises a second coating (432, Fig. 4) comprising a second biologically active material disposed on at least a part of the surface of the second stent proximate the first end of the second inner stent (Fig. 4 and Paras.[0037], [0025], and [0030]); and a outer stent (420, Fig. 4) that comprises a third coating (422, Fig. 4) comprising a third biologically active material disposed on at least a part of the surface of the outer stent (Fig. 4 and Paras.[0037], [0025], and [0030]).

Pinchuk et al and Brightbill are analogous art because they are from the same field of endeavor, stent.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Pinchuk et al and Brightbill before him or her, to modify

the system of Pinchuk et al to include three stents such that each of them comprises a coating comprising a biologically active material disposed on at least a part of the surface of each of the stents and proximate the first end of the first stent and first end of the second stents as taught by Brightbill.

The suggestion/motivation for doing so would have been to minimize undesirable reactions such as inflammation, infection, thrombosis, and proliferation of cell growth that occludes the passageway (Brightbill, Para.[0006]).

Therefore, it would have been obvious to combine Brightbill with Pinchuk et al to obtain the invention as specified in the instant claim.

9. Claims 9, 12, 22, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al (US Pat. No.: 6,348,066) in view of Brightbill (US Pub. No.: 2003/0204245) as applied to claims 4, 11, 19, and 24 above, and further in view of Yang et al (US Pat. No.: 6,258,121).

In regard to Claims 9, 12, 22, and 25, Pinchuk et al and Brightbill discloses all the limitations of the claims and each of the stent coatings comprises a polymeric material (Brightbill, 412 coating for first stent, 432 coating for second stent, and 422 coating for outer stent).

Pinchuk et al and Brightbill do not appear to disclose that the biological active material of coating disposed on each stent comprises paclitltaxel.

However, Yang et al explicitly disclose a stent that has a coating comprising a polymeric material and Taxol which is also know as paclitltaxel (Yang et al, see Abstract).

Pinchuk et al, Brightbill, and Yang et al are analogous art because they are from the same field of endeavor, stent.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Pinchuk et al, Brightbill, Yang et al before him or her, to modify each of the stents in the system of Pinchuk et al in view of Brightbill to include a stent coating comprising a polymeric material and paclitltaxel as taught by Yang et al.

The suggestion/motivation for doing so would have been to inhibit restenosis after the stent is deployed in a body (Yang et al, see Abstract).

Therefore, it would have been obvious to combine Yang et al with Pinchuk et al and Brightbill to obtain the invention as specified in the instant claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JRO

/Darwin P. Erezo/
Primary Examiner, Art Unit 3773